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GUIDELINES FOR EVALUATING AN ESSENTIAL DRUGS PROGRAMME



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PRODUCTION

The commitment to implement an Action Programme on Essential Drugs (APED) implies a parallel commitment to evaluate progress toward that goal. Progress can either be evaluated during implementation of the programme, i.e., on-going evaluation/review and after completion of the programme, i.e., ex-post evaluation.

On-going evaluation (sometimes called review) is an integral part of programme management and is primarily done in order to analyse and propose solutions to problems of implementation and operation, some of which may already have been identified by the monitoring system (see separate guidelines). The main purpose of ex-post evaluation is to review the experience of the programme as a basis for future policy formulation and programme design. The Guidelines in this document have been designed to accomplish on-going as well as ex-post evaluations.

An evaluation consists of measuring programme effectiveness and efficiency. Programme effectiveness is defined as an analysis of the results obtained in relation to the objectives of the programme, whereas programme efficiency is more an analysis of how resources are being spent in relation to cost and service provided. To state it in another way, programme effectiveness is concerned with the outcome, whereas programme efficiency is concerned with the process.

The GUIDELINES FOR EVALUATING AN ESSENTIAL DRUGS PROGRAMME have been divided into two main parts. One is called PROCEDURES FOR EVALUATION OF AN ACTION PROGRAMME ON ESSENTIAL DRUGS and the other is called MANUAL FOR CONDUCTING AN EVALUATION OF AN ACTION PROGRAMME ON ESSENTIAL DRUGS.

The PROCEDURES consist of a number of questions which will be helpful in measuring programme effectiveness and efficiency. The PROCEDURES are quite comprehensive and detailed. This is intentional, because it has not been the idea to introduce a standard format for evaluation of an essential drugs programme, the reason being that the programme in one country is often very different from the programme in the neighbouring country and each must be treated individually. It has therefore been decided to prepare the PROCEDURES as a "cook-book" from which the "menu" can be chosen depending on the individual programme and also on the emphasis of the evaluation. In newly established programmes the emphasis might be more on the central functions of the programme whereas in more advanced programmes the emphasis might be more on the periphery, i.e., rational use of drugs. However, no guidance can be given because it will always depend on the actual situation. It is therefore necessary, long before the evaluation, to assess the actual situation and decide the right evaluation protocol.

The MANUAL outlines the necessary steps involved in carrying out an evaluation from the time the decision to evaluate is taken to the time the evaluation report is completed and discussed among high-level decisions-makers. The MANUAL discusses some of the necessary steps involved in fitting a country evaluation protocol together. The MANUAL has been adopted from the manual for conducting primary health care reviews, SHS/PHC/REVIEW/84/0, 1984.

The target group for these GUIDELINES is the individuals who have a good knowledge of an essential drugs programme. Thus, they can be used by the programme management or by members of an independent evaluation mission.

Geneva, November 1985

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PROCEDURES FOR EVALUATION OF AN
ACTION PROGRAMME ON ESSENTIAL DRUGS (APED)



PROCEDURES FOR EVALUATION OF
AN ACTION PROGRAMME ON ESSENTIAL DRUGS (APED)

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Note: These procedures are in accordance with the method and glossary used in the "Health for All" series:

- no. 4 - Development of Indicators for Monitoring Progress towards Health for All by the Year 2000 (1)
- no. 5 - Managerial Process for National Health Development (2)
- no. 6 - Health Programme Evaluation; and (3)
- no. 9 - the Glossary of Terms used in the "Health for All" Series, nos.1-8 (4)

The number in brackets above and in the PROCEDURES refers to the references in sect

EXECUTIVE SUMMARY: OVERALL CONCLUSIONS AND RECOMMENDATIONS

The most important phase of the evaluation exercise consists of stating overall conclusions and recommendations.

a) Overall conclusions

On the basis of the analysis of components and functions (see sections 4 and 5), a concise narrative evaluation statement shall be provided.

b) Recommendations

Most recommendations will be the result of the above-mentioned analysis. The recommendations must include information on who will be responsible for the necessary action or approval and when it is required.

1. SUMMARY BACKGROUND INFORMATION ON COUNTRY AND HEALTH CARE SYSTEM¹

1.1 GENERAL CHARACTERISTICS

It is not necessary to include a general description of the country's geography, climate, ethnic and religious variations, social structure, transport and communication facilities etc., in the evaluation report. A short reference to relevant reports will be sufficient.

1.2 POLITICAL/ADMINISTRATIVE SUBDIVISIONS

Describe briefly and give a diagram.

1.3 POPULATION

Give the total population based on the last census and broken down into age groups and regions. If relevant, give figures on migration and refugees.

1.4 NATIONAL INDICATORS

State the rate of the following national indicators today and 10 years ago: crude birth rate, crude death rate, natural growth rate, infant mortality rate, neonatal mortality rate, mortality rate 1-4 years, maternal mortality rate, life expectancy at birth and literacy rate (male and female).

1.5 HEALTH SYSTEM

Describe the Ministry of Health (MOH) organization in general with no particular reference to the APED programme as this will be done in section 2.2.

¹ Information on country and health care systems should be obtained before the evaluation. If a PHC review has been carried out recently (last 2-3 years), it will be enough to make a reference to this review.

2. BRIEF DESCRIPTION OF THE GENERAL FEATURES OF THE APED PROGRAMME

2.1 HISTORY: Dates of historical milestones in the development of the programme (formation of a drug committee, policy formulation, legislation, ordinance, etc.) and dates when plans (appraisal reports, plan of operation) were written, adopted, revised; when the programme started to operate; when national and expatriate staff were in place, etc. (attach copies of reports).

2.2 PROGRAMME OBJECTIVES, INDICATORS AND TARGET GROUP: State the overall programme objectives, indicators (variables that help to assess the extent to which the objectives being obtained) and target group (which group in society will be the main receiver of the programme).

2.3 PROGRAMME STRATEGY: State the programme strategy. The strategy should in broad terms describe how procurement, distribution, training, selection and quantification of drugs, health education and policy and legal matters have been designed. The detailed description can be found in section 5 (Assessment of efficiency).

2.4 ORGANIZATIONAL LOCATION

a) Give diagram and describe location within MOH, including formal and informal relationships with primary health care (PHC), Maternal and Child Health (MCH), Expanded Programme on Immunization (EPI), Diarrhoeal Diseases Control (CDD), hospital and laboratory services, health education, environmental sanitation, etc.

b) Describe relationships with other ministries, including coordination and planning.

c) Describe the relationship with nongovernmental health programmes (NGO's), their support and participation in the APED programme and possible conflicting areas.

2.5 ORGANIZATIONAL STRUCTURE of APED (from central level to regions and peripheral units). Attach an organizational chart.

2.6 MANAGEMENT STRUCTURE OF APED

a) Committee: Does a steering committee (or other committee) handling APED matters exist? If so, give date established, membership, and indicate dates of past meetings.

b) Management: Who is in charge of the daily management. Attach job description as annex.

c) Expatriate(s): How many expatriates have been employed? If so, give titles and responsibilities and attach job descriptions as annex. Length of expatriate contracts?.

d) Describe lines of authority and responsibility from Programme Director to regions and peripheral units.

e) Describe lines of authority from higher level to Programme Director.

2.7 PERSONNEL identified with APED

a) Persons (excluding the Programme Director) responsible for APED programme activities at central level:

Title	How long in post	Special training	Responsibility	Job description yes/no

b) Other persons with responsibilities for APED programme activities at regional and peripheral levels:

Facility (i.e., warehouse, health centre, dispensary, training school)	Professional category	Nature of responsibilities	Job description yes/no

2.8 BUDGET

a) APED Programme budget funds approved:
in 1000 (local currency)

Category	Past year 19__		Current year 19__		Next year 19__	
	Government	Other	Government	Other	Government	Other
Purchase and distribution of - essential drugs and vaccines - essential equipment - dressings						
Salaries & allowances						
Supplies						
Travel & transport						
Rent						
Capital costs						
Other - specify						
TOTAL						

Note: If a distinct budget for APED has not been established, estimates of the above amounts should be made.

- b) Non-financial support: list all APED programme assistance in the form of supplies (excluding essential drugs), personnel, etc. (including monetary equivalents where possible)
- c) Commodity support: list the amount of essential drugs, etc., donated to the programme and the monetary equivalents.
- d) Conversion rate: What is the conversion rate to the US dollar?

2.9 GOVERNMENT AND DONOR INPUTS: describe with reference to:

- a) Personnel
- b) Supplies and equipment
- c) Training
- d) Funds
- e) Commodity support
- f) Other (specify).

2.10 HEALTH AND SUPPLY PERSONNEL INVOLVED IN THE APED PROGRAMME

Region	Number and category of sanctioned posts, e.g., no of physicians, nurses, storekeepers, etc.			
Total no. of sanctioned posts				
Total no. of occupied posts				
For occupied posts: rate per 1000 population				

2.11 FACILITIES WITHIN THE APED PROGRAMME

Region	Hospitals	Urban health centres	Rural health centres	Urban dispensaries	Rural dispensaries	Village health post	Other
Total							

3. ECONOMIC AND SOCIOECONOMIC ASPECTS OF THE APED PROGRAMME

The economic and social environment of the country will have had a significant impact on the Essential Drugs Programme implementation. Some basic economic and social data which can be gathered in the field will be helpful in evaluating the economics of the Programme. Main sources of data in the field are likely to be the Ministries of Plan, Finance, Trade, Health, and Social Affairs; there may also be research institutions, universities, multi-national and bilateral aid organizations which are willing and able to share information. Local companies and importing agencies may also have useful information. Standard sources of economic and financial data, and of trade statistics are the International Financial Statistics published on a regular basis by the IMF; the annual World Development Report of the World Bank; Trade and Development Statistics of UNCTAD. The IMF reports are particularly useful sources for country-specific rates of inflation, exchange rates, price information and information on government budget allocations and foreign exchange expenditures.

The basic elements to be included in the analysis are described below. Depending on country circumstances and the availability of data, it may not be possible to cover all the points. If this is the case, it would probably still be useful to include a qualitative "best guess" appreciation of the situation, detailing the assumptions used.

3.1 LEVEL OF DEVELOPMENT

Key indicators here are the rate of population growth, the total population, the gross national product per capita, literacy and school attendance rates, breakdown between urban and rural population, infant mortality rate, life expectancy at birth, and any other relevant information such as whether the country is an oil producer, etc. A good source for this data is the World Development Report.

3.2 IMPORTATION OF DRUGS: Trade, balance of payments, foreign exchange situation and import mechanism.

In most countries, the majority of drugs or raw materials will have to be imported and the balance of trade and the availability of foreign exchange will have a significant effect on the success and continuation of the essential drugs program. Key indicators include the percentage of total imports devoted to drug (this can be estimated roughly if not precisely calculated, by finding out total imports from IMF statistics and estimating total imports of drugs, both public and private; it may be interesting to compare with such imports as gasoline and fuel, food, wood products, vehicles, etc.); the sources of the imported drugs; any restrictions affecting the import of drugs or raw materials, including the granting of import licences or foreign exchange licenses; exports of locally produced drugs, if any, and re-export of imported drugs. Exchange rates (official and semi-official) can be found in the IMF statistics, but market rates must be gathered anecdotally in the field and used with care, since they usually undervalue the currency, and governments are often sensitive about the subject. A qualitative appreciation of how serious the foreign exchange shortage is would be useful.

The role of foreign donors and aid agencies in alleviating the foreign exchange shortage may be significant; an estimate of how much foreign exchange they supply for drug purchases would be useful.

It is also useful to describe the mechanism of importation of drugs. What is the breakdown between public and private imports, and is the same process followed for both? A description of the main organizations involved in drug imports is useful, including their legal framework and status, their respective volumes of imports, their principal clients, whether they are subsidized by the government, etc.

If import duties are applied to drugs what are the percentages applied to different types of drugs, etc.

3.3 PRICES

How are prices calculated, in both the public and private sectors? What is the breakdown, with transport, profit margins, distribution costs, etc.? What margins are permitted to pharmacists? If possible, price level data should be gathered for 15-20

essential drugs, going back to the beginning of the program to show whether prices have dropped and by how much. What are comparable prices in the private sector, if it exists side by side?

3.4 COST RECOVERY

If a cost recovery mechanism was included as part of the essential drugs programme, describe it and comment on the success or lack thereof. Was the intention to recover all the costs of drug supply, or only part of those costs? Was adequate provision made for expansion of the coverage and for increased demand for drugs, and for inflation? What provision was made for indigent patients and chronic diseases? Did the responsible personnel collect fees as expected? Could the scheme be replicated in other countries? How did prices for drugs correspond with people's willingness and ability to pay?

3.5 BUDGETARY ALLOCATIONS AND EXPENDITURES FOR HEALTH AND DRUGS

This section deals with the place of the essential drugs programme in the health sector expenditures overall, the health sector's share of overall government expenditures, and allocations within regions, between urban and rural facilities and programs, and the role and importance of the private sector.

Key questions are:

- a) What is the percentage of the overall government budget allocated to health? Include both Ministry of health and expenditures by other institutions, such as armed forces, education, national hospitals, semi-government procurement agencies, etc.--these may be significant and even exceed expenditures by the Ministry of Health. Show the trends over the past five years.
- b) What is the share of pharmaceuticals and vaccines in national health expenditures (MOH and others)? If possible, breakdown between essential and other drugs.
- c) What is the breakdown between recurrent and investment costs in the health budget? What share is allocated to personnel ? transportation? other significant categories?
- d) What type of investments are planned, and what kind of recurrent budget implications can they be expected to have? What will be the impact on the budget allocations for drugs?
- e) What is the breakdown between urban and rural programs? Preventive and curative?
- f) How important is the private sector? Estimate the expenditures on private medicine if possible. Include social security schemes, armed forces, and other major providers if applicable.
- g) What are the major sources of finance for the health system? (public revenue at central level, regional and local revenues, household expenditures, insurance schemes, non-governmental contributions, foreign aid and other external inflows. Describe briefly activities of major donors in health sector.

Note: Several recent WHO documents provide explanatory detail and propose tabulation on specific aspects, reference (5), (6), (7), (8), (9), and (10).

4. ANALYSIS OF EFFICIENCY

The analysis of efficiency consists of a comparison of the results obtained in relation to the efforts made and resources used as well as the degree to which actual implementation complies with the planned implementation.

Before reviewing the efficiency of the programme, the following three steps are recommended:

Step one

Look separately at each component as it appears in the original project document (appraisal report or plan of operation).

An APED programme is likely to have at least the following components:

4.1 Selection of drugs, equipment and dressings

4.2 Logistics

- 4.2.1 procurement (procurement methods, contract terms, locating and selecting suppliers, procuring, monitoring supplies performance, quality assurance, local production of pharmaceuticals or import)
- 4.2.2 distribution (receiving and inspecting, storage and warehousing, inventory control, supply, delivery)
- 4.2.3 logistic support (maintenance and repair, environmental management of health facilities, records and reporting)

4.3 Manpower development

- 4.3.1 formal training
- 4.3.2 supervision

4.4 Health education and information

4.5 Policy and legal aspects

Step two

For each component state the immediate objectives, inputs, activities, outputs and assumptions and list the indicators and the portion scheduled for completion/provision by the time of the evaluation (see figure).

Figure

	Immediate objective ¹	Inputs ²	Activities ³	Outputs ⁴
List aims	x	x	x	x
List indicators ⁵	x			
List portion scheduled for completion(c)/provision(p) by the time of the evaluation		x (p)		x (c)
Review progress	x	x		x
List assumptions ⁶	x	x	x	x

- ¹ Immediate objectives: express the particular effect which the component is expected to achieve, if completed successfully and on time, e.g., "train selected health planning officers, medical officers, storekeepers and clerks in managing the drugs supply system with emphasis on procurement, storage, distribution, supervision and monitoring".
- ² Inputs: are money, personnel, materials, services, etc. to be provided by the benefitting country and/or WHO and other donors, e.g., "1 technical expert to participate in drug supply management training or funds for a national level workshop on drug supply system, etc.".
- ³ Activities: are the actions, the training and other substantive tasks to be carried out by the programme management, e.g., "2 weeks of training of mid-level managers and drug supply operational staff in the drug supply system".
- ⁴ Outputs: are the product of completed activities, e.g., "10 mid-level managers and 25 operational staff trained in the drug supply system".
- ⁵ Indicators: are variables that help to measure change, e.g., "an improved drug supply system, measured as the availability at any given time at each service delivery point of at least 90% of the essential drugs assigned to that level".
- ⁶ Assumptions: is the term for external influences, factors, situations and conditions which are necessary for project success, but which are largely or completely beyond the control of programme management, e.g. "retention of trained personnel in functions for which they were trained".

Step three

Analyse efficiency by comparing actual with planned achievements and assess whether the result could have been obtained in a better and more economical way. In order to perform this analysis, a number of questions have been developed for each component. Some will be relevant for the actual situation, some not. The following sections 4.1-4.5 describe the questions that could be asked when comparing actual with planned achievements.

4.1 SELECTION

4.1.1 SELECTION OF DRUGS

- a) Is there a national list of essential drugs?
- b) If yes, is this list only for the public sector or for both sectors?
- c) Is it implemented?
- d) Are there lists by level of use?
- e) If yes, how many items are on these lists?

Ideal number of items

Ref: Village health worker (VHW)	6-10 (see table 1--example from a country)
Dispennsary/health centre	30-40 (see table 2--example from a country)
District hospital	60-100
Consulting hospital	200

- f) Are all items on the WHO list of essential drugs?(11) How many are not?
 - If not, i) Do these items comply with the WHO guidelines for essential drugs?(11) pages 7-10
 - ii) Can their inclusion be justified?
 - iii) Who is determining these "exceptions"?
- g) Compare the actual lists with the original ones included in the first plan of action. Try to understand the why of deletions and additions (need, demand etc.)
- h) Are all items on the list really essential for that level of health care?
- i) Is the list complete?

All the therapeutic groups should be considered, but inclusion of drugs on the list under study should depend on local conditions, specific prevalent diseases, capacities of the health workers involved and integration with other programmes (e.g., EPI, TB, etc.).

Table 1 - example from a country

LIST OF DRUGS FOR VHW:

Analgesic

Acetylsalicylic acid tab. 300mg

Anti-helmintic

Piperazine tab. 500mg

Anti-malarial

Chloroquine tab. 150mg base

Anti-anaemia

Ferrous salt tab. 200mg

Folic acid tab. 5mg

Dermatological

Benzyl Benzoate lotion

Oral Rehydration Salt

Ophthalmic

Tetracycline eye ointment 1%

Table 2 - example from a country

LIST OF ESSENTIAL DRUGS FOR RURAL HEALTH CENTRES/DISPENSARIESAnaesthetic, local

Lidocaine 2%

Ear drops

Chloramphenicol ear drops 5%

Analgesics

Acetylsalicylic acid tab. 300mg

Paracetamol tab. 500mg

Oral Rehydration SaltOphthalmic

Tetracycline eye ointment 1%

Anti-allergic

Chlorphenamine tab. 4mg

Oxytocic

Ergometrine inj. 0.2mg/ml

Anti-bacterial drugs- Penicillins

Procaine Benzyl Penicillin

inj. 4.8 mega U. + inj. water

Triple Penicillin mixture

inj. + water for injection

Phenoxymethyl Penicillin syrup
250mg/5ml

Phenoxymethyl Penicillin tab. 250mg

Plasma expander

Dextran 70 I.V. infusion

Psychotherapeutics

Chlorpromazine tab. 25mg

Chlorpromazine inj. 50mg/2ml

- Antibiotics, other

Tetracycline capsules 250mg

Sulfadimidine tab. 500mg

Respiratory tract drugs

Ephedrine tab. 30mg

Adrenaline inj. (1:1000) 1ml

Vitamins

Vitamin A tab.

Anti-epileptic, sedatives

Phenobarbital tab. 50mg

Phenobarbital inj. 120mg/2ml

Anti-helminthics

Niclosamide tab. 500mg

Piperazine tab. 500mg

Mebendazole tab. 100 mg

Anti-malarial/anti-protozoals

Chloroquine tab. 150mg base

Chloroquine syrup 50mg base/5ml

Quinine inj. 300 mg/ml

Metronidazole tab. 200mg

Anti-anaemia

Ferrous Sulphate tab. 200mg

Folic Acid tab. 5mg

Anti-schistosomal

Metrifonate tab. 100mg

Antacid

Magnesium Trisilicate tab. 250mg

Carthartic

Senna tab. 7.5mg

Dermatological preparations

Gentian Violet crystals

Hydrocortisone 1%

Benzyl Benzoate lotion

Benzoic acid + salicylic acid
(Whitfield's ointment)

4.1.2 SELECTION OF ESSENTIAL EQUIPMENT AND DRESSINGS

Is there a list of essential medical materials (dressings, needles, equipment and laboratory materials)?

If so, a comparison can be made with the following examples:

- Equipment list, Ministry of Health, Kenya, for Rural Health Facilities (Table 3)
- List of dressing material for emergencies, Red Cross (Table 4)

Table 3

List of essential equipment items needed with the essential drugs in rural health facilities

Equipment item	UNIPAC code	Required	
		HC/HSC	DISP
Bottles Albustix urine tests	0921100	1	-
Luer syringes 2 cc. nylon	0785670	40	20
Luer syringes 10 cc. (autoclavable)			
- not disposable nylon	07856784	10	2
Hypodermic needles Luer s/s	0750500	10	-
(children)			
Hypodermic needles Luer s/s	0749500	50	25
Clinical thermometres F	0481050	10	5
Auroscope	0660000	1	1
Sphygmomanometer aneroid	0683000	2	1
Stethoscope	0686000	4	1
Test tube racks	0968518	1	-
Test tubes	0978995	20	-
Spirit burner	0515500	1	-
Test tube holder	0930000	1	-
Monocular microscope	0960000	1	-
Slides	0969000	1	-
Slide covers	0934001	1	-

Source: Government of Kenya, Ministry of Helth, New Management Systems of Drug Supplies to Rural Health Facilities, Training Manual, May 1982.

Table 4

Dressing material set

1 parcel containing:	
1 x 10	rolls gauze bandages 6 cm x 10 m
2 x 10	rolls gauze bandages 8 cm x 10 m
2 x 12	elastic bandages 8 cm
1 x 12	elastic bandages 10 cm
2 x 100	sterilized gauze pads 10 x 10 cm
1 x 100	sterilized gauze pads 10 x 20 cm
50 x 2	sterile covers sponges 7,5 x 10 cm
1 kg	absorbent cotton wool
5	triangular bandages
1	adhesive bandage 5 m x 6 cm
1	dheseive bandage 5 m x 8 cm
1 x 12	rolls adhesive tapes 2,5 cm x 10 m
1 x 6	rolls adhesive tapes 5 cm x 10 m
1 litre	skin desinfectant
1 pair	scissors + 1 forceps

Source: International Committee of the Red Cross, Medical Division Standard Emergency Units, Geneva 1983. Price appr. 200 S.fr. (84) covers 50-100 persons in an emergency situation.

4.2 LOGISTICS

This part of the evaluation deals with LOGISTICS. Logistics is defined as the process of procuring, maintaining and transporting supplies.

When evaluating the performance of the logistic system, a number of questions should be raised. In formulating relevant questions, extensive use has been made of reference (12) and (17).

4.2.1 PROCUREMENT

Procurement is the process of acquiring supplies and it involves i) choosing of procurement method, ii) specification of contract terms, iii) locating and selection of suppliers, iv) monitoring supplier performance, and v) quality assurance of drugs.

A. PROCUREMENT METHOD

a) Which of the following four (or combination of the four) procurement methods are being used in procuring drugs, equipment and dressings:

- 1 open tender (public and unrestricted bid)
- 2 restricted tender (suppliers must be registered and approved in advance)
- 3 negotiated procurement (suppliers are well known and can be approached directly)
- 4 direct procurement (suppliers' wholesale or retail prices are used directly).

Do the methods used ensure the availability of safe and effective drugs of acceptable quality at the lowest possible cost? Are the obtained prices in accordance with prices in the commercial market? Compare with UNICEF prices (17).

b) Are drugs labelled in accordance with standardized labels of APED programmes, e.g., generic name, dosage strength, presentation, quantity contained, manufacturing date including expiry date, batch number, any special usage and storage precautions and name and address of manufacturer.

B. CONTRACT TERMS

Analyse existing contracts and evaluate whether they maximize the likelihood of satisfactory supplier performance, without leading suppliers to raise prices? The contract should at least have provision for the following:

- trade terms
- price and currency
- payment terms
- quality standards
- nomenclature and labelling
- product specification
- financial guarantees
- delivery date
- patent provisions
- packaging
- expiry date.

C. LOCATING AND SELECTING SUPPLIERS

a) Describe the supply sources (including percentage of each source) for drugs, equipment and dressings, e.g., government production, local private manufacturing, foreign manufacturing, donors, international procurement services, etc. and analyse the reliability of the suppliers. An example of a system to evaluate new suppliers can be found in reference (12), page 154.

b) Assess whether the location and information about new suppliers is sufficient. Are new suppliers located through national or international advertisement, international procurement services, etc.? Is information about new suppliers gathered informally, by test purchases or formal registration (an example is given in reference (13), pages 6-9)?

c) Analyse whether new suppliers are chosen according to, e.g., price, quality, past performance, delivery date, etc.

D. PROCURING

Analyse the system of procuring and check whether the answer to the questions are positive:

- a) Is there a standardized supplies list?
- b) Are there sufficient staff adequately trained?
- c) Are there sufficient forms and records?
- d) Are donations made in accordance with standardized supplies list?
- e) Is there a defined supply period?
- f) Are stock records up to date?
- g) Have re-order levels for major stock items been identified?
- h) Are reserve stocks maintained?

E. MONITORING SUPPLIER PERFORMANCE

Does there exist a formal monitoring system for evaluating supplier performance? If so, does it provide the following information?

- a) recording of supplier participation,
- b) response to inquiries,
- c) delivery time,
- d) adherence to delivery instructions,
- e) provision of documents,
- f) packing and labeling,
- g) cost improvement suggestions.

More details can be found in reference (12), page 157.

F. QUALITY ASSURANCE

The purpose of quality assurance in an essential drugs programme is to make sure that each drug reaching the patient is safe, effective and acceptable. Analyse whether the quality control system ensures safe, effective and acceptable drugs.

A well functioning Quality Assurance System should be based on stated policies and procedures aimed at assuring drug quality; access to a drug quality control laboratory; well trained and adequately supervised quality control inspectors; procurement of drugs in accordance with Good Manufacturing Practices (GMP) (14) and international pharmacopoeias and participation in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (14).

When evaluating the Quality Assurance System the following questions might be helpful:

- a) What methods are used to assess and maintain the quality of drugs from supplier to end user (patient)? Is there a plan for taking samples of the drugs? If so, which? Is it realistic?
- b) Has bad quality of drugs ever been an issue in the programme? In what way? What effect has this had on the public health? On the programme? On health personnel?
- c) To what extent is physical inspection made of the drugs received in the central medical store? Are the inspectors well-trained and adequately supervised?
- d) Are laboratory analyses ever used to assess drug quality? If so, on what basis are samples chosen? Who performs the analyses? Is the testing laboratory reliable?
- e) If drugs are received from suppliers in kits, what procedures are used to inspect the kits?

- f) What are the conditions during transportation from supplier to dispensary? Can drugs seriously affected by these conditions? What has been done to change this situation?
- g) Are storage facilities periodically evaluated i) at port-of-entry, ii) at central warehouse, iii) at district and regional warehouses, iv) at health centres and dispensaries? If so, what are the procedures and who is responsible and what training do they have?
- h) Is there a system for village health workers, nurses, physicians and other personnel at the peripheral level to report problems with drug quality? If so, which system?

G. LOCAL PRODUCTION OF PHARMACEUTICALS OR IMPORT

- a) Describe the local pharmaceutical production capability doing:

- primary manufacturing (the production of active medicinal substances and other ancillary substances used in pharmaceutical formulations);
- secondary manufacturing (the processing of medicinal substances, usually together with ancillary substances, to produce the required pharmaceutical dosage forms);
- packaging (the packaging of dosage forms in manners appropriate to the nature of the preparations and their intended use, conditions of transportation, and expected conditions and time of storage).

and assess the potential for the future (Does government policy promote local production?)

- b) Are locally-produced drugs essential?

- c) Assess whether locally-produced drugs are competitive with similar drugs on the international market?

4.2.2 DISTRIBUTION

Distribution deals with all of the activities required to receive drugs from the suppliers and to move them safely, securely, and expeditiously to the many points in the health care system.

H. RECEIVING AND INSPECTING

Receiving

Evaluate whether receiving procedures are based on:

- a) Goods received are the same as goods ordered
- b) Adequate storage and holding facilities at the point of entry
- c) One person responsible for receiving supplies
- d) Customs clearance work smoothly
- e) Adequate warning of arrival of drugs

Inspecting

Analyse whether inspecting procedures are based on:

- f) Established system for inspection of supplies
- g) One person responsible
- h) Sufficient staff to do the work
- i) Adequate documents and forms for inspection
- j) Action taken and results recorded when discrepancies are found
- k) Unauthorized substitutions of goods rejected
- l) Price charged compared with price quoted
- m) Physical inspection carried out on all incoming goods
- n) Adequacy of packing checked
- o) Check for quality of received supplies

I. STORAGE AND WAREHOUSING

Each store should be assessed in relation to:

a) Physical arrangement of stores (Central Medical Store and regional/district stores)

Structure:

- Is the building structurally sound?
- Is there adequate light?
- Is there adequate cross-ventilation?
- Is the floor strong and even?
- Is it vermin, bird and insect proof?

Security:

- Are all doors lockable?
- Are roof and air vents secure?
- Are all windows barred?
- Is there a control system for visitors?
- Have there been no significant losses from the store?

Services:

- Is there suitable artificial lighting?
- Is there drainage?
- Is there fire-fighting equipment and is it regularly checked?
- Do staff know how to use it?
- Is there an alternative supply of electricity for cold rooms and refrigerators?

Capacity:

- Is the store big enough?
- Are there special stores for toxic/inflammable goods separate from the main building?

b) Handling facilities

- Is there equipment to move stores around the warehouse?
- Is there protective clothing for porters, e.g., for those working in -20 C cold rooms?
- Are there enough shelving racks and cupboards to hold your stores?

c) Suitable staff

Are there suitable staff for the following:

- Management and control of store?
- Receiving and issuing supplies?
- Handling supplies?
- Maintaining stock control?
- Maintaining building, grounds and safety equipment?
- Maintaining sanitary facilities?
- Maintaining specialist storage space, e.g., refrigerators and freezers?
- Maintaining cleaning schedules?

- Does each category have a job description?
- Are there facilities for on-the-job training and retraining?

d) Standard list of stock items

- Is there a specific description for each stock item?
- Are all stock items included on the list?
- Is the list regularly updated?
- Is the list distributed to sub-stores and units?
- Do received orders use the same wording to describe items as those in the list?

e) Special storage

- Are controlled drugs kept in a double locked store?
- Are contaminated supplies, e.g., disinfectant, kept in a separate store?
- Are inflammable goods kept in a special separate store?
- Are there sufficient and suitable refrigerators and freezers, or cold rooms for vaccines and other heat-sensitive supplies?
- Are there secure stores for small items such as dental and surgical equipment?

f) Supervision

- Is there a supervisor?
- Is there a schedule for supervisory visits?
- Is there a supervisor's checklist?
- Is there regular temperature recording for coldroom, refrigerators and freezers?
- Are drugs and supplies physically checked regularly?
- Are staff encouraged to make suggestions?

g) Wastage

- What is the wastage rate for drugs, i.e., drugs which do not reach the intended population? Causes of wastage could be i) drugs expired, ii) physical damage, iii) damage by climate (sun, heat, humidity), iv) pilferage, and v) losses.
- What is the procedure for expired drugs? Are they being consumed or are they being returned?

J. INVENTORY CONTROL

Analyse the inventory control system and check whether the answer to the following questions are positive:

a) Recording of inventory

- Is the information recorded the same as the quantity of stock in store?
- Is there a schedule for resupply?
- Are inventory reports regularly received from all sub-units?
- Are inventory reports from sub-units regularly checked?
- Are there sufficient quantities of all inventory forms?
- Are there sufficient staff?
- Are recording forms regularly reviewed and brought up to date?

b) Sufficient stock level

- Are there reserve stocks sufficient to meet reasonable demand?
- Have all requests been supplied in the last year?
- Are all supplies within their expiry date?
- Are predetermined maximum stock levels set for most items?
- Are all items below the maximum stock level?
- Are allowances made for seasonal demand?
- Is stock rotated on a "first in, first out" basis?
- Is there a defined system for resupply?
- Is there a policy for disposal of damaged or expired supplies?
- Is the cost of maintaining supplies well-balanced, e.g., not too frequent supply?
- Is there an effective means of communication between each link in the supply chain?
- Is there regular supervision?

c) Inventory control at health centres/dispensaries

- Is there a regular storekeeper? Has he/she been trained? Who is supervising?
- How often are the health centres/dispensaries out of stock?

K. SUPPLY

Analyse the supply system and check whether the answers to the following questions are positive:

Documents used for ordering supplies

- Do forms have all necessary information?
- Do staff understand forms?
- Are forms completed correctly?
- Are there any unnecessary delays?

Supplies at sub-stores

- Are there clear supply procedures?
- Are there established supply intervals?
- Are quantities compared with consumption?
- Are quantities compared with morbidity?
- Are supplies within their expiry dates?
- Are heat-sensitive supplies kept cold?
- Do all sub-stores have stocks of all essential supplies?

L. DELIVERY

Evaluate the delivery system and check whether the answers to the following questions are positive:

Distribution system

- Are there adequate sub-stores?
- Are there established delivery policies?
- Is the time taken to travel to each sub-unit known?
- Are the shortest routes used?
- Are there contingency plans to cope with breakdowns in the normal distribution system

Transport plan

- Have alternative uses of transport been assessed in establishing the preferred transport policy (e.g., rail, air, road haulers, other ministries' transport)?
- Has the most economical and practical mode of transport been chosen?
- Are vehicles' needs automatically received for additions and replacement regularly?
- Is there a transport manager?

Transport facilities

- Are there sufficient working vehicles to meet your needs?
- Are there alternative types of vehicles to meet different needs?
- Is there a limited number of makes in use?
- Are there adequate supplies of fuel?
- Are there sufficient numbers of trained drivers?
- Is there specialized transport for heat-sensitive suppliers?
- Are vehicles used to their best advantage and not limited to a single part of the supply system?

4.2.3 LOGISTIC SUPPORT

M. MAINTENANCE AND REPAIR

Assess the maintenance and repair system and check whether the answers to the following questions are positive:

Maintenance and repair of vehicles

- Are there maintenance schedules for routine maintenance?
- Are there adequate stocks of spare parts?
- Are there sufficient numbers of trained mechanics?
- Are there job specifications for all staff?
- Are there sufficient equipped and accessible workshops where vehicles can be maintained under cover?
- Are there suitable garages where vehicles may be kept under cover?
- Are there adequate safety facilities and fire appliances?
- Are there repair and maintenance manuals and spare parts for all categories of vehicles?
- Are there set procedures for vehicle repair?
- Do drivers keep vehicle logs?
- Do speedometers work?
- Are vehicle mileages logged?
- Are there adequate stocks of: spare parts? lubricant? consumables, e.g., oil filters? 1 bulbs and tyres?
- Are there adequate stocks of forms and records?

Maintenance and repair of equipment

- Are there maintenance schedules for routine maintenance of major items of equipment?
- Are refrigerator user guides in use?
- Are there sufficient numbers of trained repairmen?
- Are there job specifications for repairmen?
- Are there sufficient equipped and accessible workshops?
- Is there an effective equipment failure report system?
- Is there an equipment status report for major items?
- Are maintenance and repair manuals and spare parts catalogues available?
- Are clinical staff trained in the routine use, care and maintenance of equipment?
- Are there adequate stocks of: spare parts for refrigerators? spare parts for freezers? fuel (gas or kerosene)? spare parts for dental equipment? spare parts for other equipment?
- Are there adequate stocks of forms and records?

Maintenance and repair of buildings

- Is there any routine maintenance of buildings?
- Is the works department responsible for maintenance of stores adequately equipped?
- Is there regular cleaning and inspection of stores?
- Is there an effective system for reporting damage to buildings?
- Are the materials necessary for repair and maintenance available?

N. ENVIRONMENTAL MANAGEMENT OF HEALTH FACILITIES

Analyse environmental management of health facilities and check whether answers to the following questions are positive:

Standard of cleanliness, hygiene and safety at stores and health facilities

Cleaning:

- Is there an adequate supply of safe water?
- Is the facility clean inside and outside?
- Is there a person responsible for keeping the facility clean?
- Is there a cleaning schedule?
- Are there enough cleaners?
- Is there sufficient equipment and cleaning materials?
- Is there adequate refuse disposal?
- Are there specific measures for disposal of dangerous or toxic substances?
- Are there any posters or notices warning staff about the importance of cleanliness?

Hygiene:

- Are there clean conditions in key areas, such as the pharmacy and kitchens?

Health units only:

- Do staff use special clothing to wear whilst in these areas?
- Are the sanitary facilities satisfactory, e.g., wash basins and W.C.s?
- Is the drainage system satisfactory?
- Are there hygiene notices posted, e.g., for handwashing?

Safety:

- Are there regulations for handling inflammable, dangerous or toxic substances?
- Is there protective clothing for those who require it, e.g., dust masks, goggles, etc.?
- Is there an adequate level of lighting and ventilation?
- Are there working fire-fighting appliances?
- Are they regularly inspected?
- Do staff know what to do in case of fire?
- Is one person designated as fire officer?
- Is there a working fire alarm?
- Are there adequate safety precautions in laboratories, e.g., fume cabinets?
- Are there first aid kits in stores and high risk areas?
- Is smoking restricted to specific areas?

RECORDS AND REPORTING

Evaluate the records and reporting system and check whether the answers to the following questions are positive:

Reporting between the periphery and mid-level management

- Are stock consumption reports routinely received each month from all peripheral units?
- Are comparisons made between stock consumption and use, e.g., doses of vaccine issued/number of doses of vaccine given/number of fillings made/quantity of amalgam used?
- Is morbidity data available?
- Are there established treatment schedules for essential drugs?
- Are comparisons made between stock consumption and morbidity data?
- Is all reported data necessary?
- Is all essential data reported?
- Is there routine feedback to the units at the periphery?

4.3 MANPOWER DEVELOPMENT

4.3.1 FORMAL TRAINING

Training for essential drugs programmes is carried out with several objectives in view mainly:

- to increase numbers of personnel with skills related to an essential drug supply management system;
- to promote increased awareness of the importance of an essential drug policy for the health status of the population;
- to increase understanding of the inter-relationship among the components of an essential drug management system: selection, procurement, logistics of storage and distribution, monitoring and evaluation, and drug use;
- to improve skills of health facility personnel in respect to better diagnoses and prescribing practices.

A. TRAINING INFRASTRUCTURE

Evaluate the training infrastructure and check whether the answer to the following questions are positive:

- Is there a single appointed focal point (training officer or training unit) responsible for organization and coordination of training activities?
- Has a formal/informal assessment been made of manpower training needs throughout the APED programme including the balance/maldistribution of trained personnel?
- Have formal/informal projections been made of training needs for the next 1 - 5 years?
- Are premises for different training purposes available and accessible?

B. NUMBERS, ACTIVITIES AND BUDGET

For both a structured training programme (on-going at regular intervals) and ad hoc training activities, compare the following questions with the Plan of Action and note discrepancies:

- How many trainees have completed training activities in the past 3-year period?
- Types of training activities?
- Numbers trained in-country, nearby country, abroad?
- Has the yearly budget allocation for training purposes been sufficient?

C. TRAINING MATERIALS

Compare the following questions with the Plan of Action and note discrepancies:

- Have specific training materials been developed?
- Have training materials been developed for health facility personnel at different levels on diagnostic procedures and prescribing drugs?
- Have training manuals for trainers been developed specifically?
- Have teaching aids - posters, slides, wall charts, etc. - been developed for different levels of health care facility?
- Have teaching/education materials been developed for patients and general public?

D. SELECTION OF TRAINEES

In the table, you will find the target groups which should have been trained by the programme.

IDENTIFICATION OF TARGET GROUPS TRAINED AND PLACE OF WORK

[illegible]

4.3.2 SUPERVISION

There is a number of ways of defining SUPERVISION. A passive definition would be to consider supervision as control procedures (records, reporting, etc.), and a more active definition would be to consider supervision as an educational tool, i.e., one-the-job training. Supervision is probably a combination of both definitions.

In relation to an APED programme, the health care system and the drug supply system must be supervised. The health care system is supervised by the medical staff, whereas the drug supply system is supervised by the logistic staff.

Medical supervision

Medical supervision is normally given by a superior (doctor) to a subordinate (para-medical assistant), but can just as well be given by a trainer, a fellow para-medical assistant who has more knowledge, or an outside person who knows how to convey the message, e.g., a teacher with knowledge about sanitation, community organization, public health, etc. To evaluate the medical supervision, the following key questions should be investigated:

- a) who is supervising whom?
- b) how often does supervision take place?
- c) does a regular schedule for supervision exist?
- d) is there a system of follow-up to see that observations are implemented?
- e) do the supervisors have the tendency to "take over"?
- f) have the supervisors been trained in how to supervise?
- g) is there transport available for supervision?

Logistic supervision

Logistic supervision is given to the periphery by the middle management and to the middle management by the senior management. Supervision should not be a system where a senior group checks on a more junior group, but rather a system to make sure that the communications system works to and from the periphery. To evaluate the logistic supervision, the following key questions should be investigated:

- are there staff identified as supervisors?
- do they have and use a regular schedule for supervision?
- are there checklists available to help them?
- is there a system of follow-up to see that observations are implemented?
- is there any static supervision (analysis of routine reports)?
- do supervisors take information down to the units as well as collecting it for higher levels?
- is there transport available for supervision?

.4 HEALTH EDUCATION AND INFORMATION

Health education and information is carried out with the objective of:

- ensuring that all health personnel in the programme area are aware of the programme, its purpose with regard to PHC and the kind of support they will be given to cope with the new situation caused by the programme
- ensuring that local opinion leaders and other elites know about the programme and its purposes and become motivated to play an active supportive role
- enabling health personnel and opinion leaders to inform the general public about the programme and its importance to improve PHC.

1. HEALTH EDUCATION AND INFORMATION AT THE NATIONAL LEVEL

- a) Is there a national health education service? If so, is this unit involved in the APED programme?
- b) Is the health education service or another service involved in ensuring that the policy and principles of essential drugs are included in the curriculum of:
 - medical students
 - nursing students
 - other health personnel
 - school teachers
 - public information personnel
 - workers in other sectors whose functions involve education for health.
- c) Describe briefly the information about essential drugs at the national level since the start of the programme specifying medium, subject matter, target population, frequency and those involved.
- d) Is there an identifiable amount budgeted at the national level for health education about essential drugs? If so, how much?

2. HEALTH EDUCATION AND INFORMATION AT THE REGIONAL/DISTRICT LEVEL

- a) Is there a health education service in the region/district?
- b) What are the means used for informing people of health problems?

3. HEALTH CENTRE/DISPENSARY LEVEL

- a) At the introduction of the programme were government officers, health personnel and local opinion leaders briefed about the programme, its rationale and the kind of activities to be carried out?
- b) Were the health personnel trained in improving their communication skills?
- c) What kind of education and information material has been produced and introduced
 - hand-outs
 - posters
 - booklets on the drug policy other
 - flip-charts for training
 - tape-recordings about drug behaviour
 - street announcements
 - song and local dramas
 - advertisement in papers
 - radio programmes.
- d) Has the logo of the programme been introduced? If so, to which degree?

e) Describe in some detail the health education and information about essential drugs in last 6 months specifying medium (play, demonstration, etc.), subject matter, target population, frequency and those involved (education department, NGO, health personnel, cultural groups, opinion leaders, etc)?

f) Does the health education and information support the programme in relation to:

- drug security, both in reporting illegal sale and ensuring safety while in the health u
- the public accepting advice from the health workers, instead of insisting on drugs?
- unnecessary use of hospital facilities?
- the public not insisting on injections instead of drugs to be taken orally?
- the public refraining from pressuring rural health staff into prescribing unnecessary drugs?

4.5 POLICY AND LEGAL ASPECTS

4.5.1 POLICY:

The national drug policy will influence in one way or another an essential drugs programme. During an evaluation, these influences have to be assessed. It will also give a clear indication of the degree of commitment of the government regarding the APED and the implementation of the concept of essential drugs.

- Is there a national drug policy?
- If yes, what are the objectives of this policy (health goals, economic goals, self-sufficiency, etc.)?
- In which aspects can this policy influence the APED (positive or negative)?
- Is there a national list of essential drugs?
- If yes, is it adopted (for the public sector or for both private and public sector)?
- What is the policy toward the private sector?
- In which ways does this policy influence the effectiveness of the APED?
- Is the government fully committed to the objective of the APED? Analyse other aspects of the drug policy in order to see if the global policy of the government is in accordance with the APED.
- Is there a National Drug Committee set up in order to draw list of drugs or to revise the existing lists?
- How many drugs are on the market?
- What criteria are used for registration of drugs; are they similar to the ones used for selecting essential drugs (11)?
- How does the parallel system influence the APED?

4.5.2 LEGAL ASPECTS

Drug legislation and regulatory control systems should assure that safe and effective drugs of good quality and for the intended uses reach the consumer.

A. THE BASIC ELEMENTS OF THE DRUG LEGISLATION

This section is dealing with most of the elements on a national drug legislation. During an evaluation all these aspects have to be assessed. The first question should be:

- Is there any distinction in the legislation between essential drugs and other drugs?
- If yes, indicate in the following questions how the essential drugs are treated differently from other drugs.
- If no, try to assess the elements in the legislation which are relevant to the APED programme. The following questions might be useful:

a) General

- What are the present laws referring to drugs?
- Is there a Drug Act?
- What basic elements are included in this Drug Act?
- Is the essential drug list endorsed by law?

b) Control of import of drugs

- What are the conditions in the legislation for importation of drugs?
- Is a licence required:
 - for imports of drugs in manufacturer's original packaging,
 - for imports of bulk drugs by the manufacturer,
 - for unregistered drugs on a case-by-case basis?
- Who is qualified to import drugs?
- Which type of licences?

c) Control of export

- What are the conditions for export of drugs?
- Is a certificate required for export?
- Are there record-keeping procedures with respect to exported drugs?
- Who is qualified to export drugs?

d) Control of manufacturers

- Is a licence required specifying the kind of formulated drug an enterprise may be allowed to manufacture based on the results of inspection of premises and equipment and on qualification of technical personnel?
- To get the licence, is it required to follow Good Practices in Manufacture and Quality Control of Drugs (industry level) (18)?

e) Control of distribution

Legislation in this area tends to avoid a chaotic distribution of drugs which could be prejudicial to the patient and ensures provision of proper storage facilities at all levels and effective supervision by responsible technical staff.

- What are the conditions in the regulations for distribution of drugs?
- Are the allowed channels of distribution (treatment establishments, pharmacies, drug warehouses, etc.) fixed by the law?

f) Drug registration aimed at controlling drug marketing

- Has an inventory of the drugs on the market been conducted?
- Has the number of pharmaceutical products been reduced?
- What kind of information is needed by the Drug Control Administration before the registration of a new drug?
- Is the WHO Certification Scheme for Products moving in International Commerce used (14)?

g) Labelling

- Are there national specifications for labelling?
- Are there provisions for control:
 - of the container?
 - of the outer package?
 - of the package insert?

For example, does package labelling require the generic name, dosage strength, presentation, quantity contained, manufacturing date including the formula, name and address of manufacturer and product expiry date, batch number, any special usage and storage precautions, name and registration number?

h) Information and advertising

- Are there regulations on how and where it is permitted to advertise drugs?
- What are these regulations?
- Is advertising prohibited in certain circumstances?

i) Scheduling

- Is there an official published national formulary?
- Is there an essential drug list enforced by the law?
- What are the conditions for sales of drugs (prescription and non-prescription drugs, etc ...)?

j) Price control

- Are there provisions in the legislation for the control of prices for drugs available on the market (maximum prices ...)?

B. THE DRUG CONTROL ADMINISTRATION

The establishment of statutory regulation presupposes its surveillance by competent personnel.

The Drug Control Administration is of prime importance because it is the body that issues the various authorizations granted, whatever the stage of the drug.

In this area, different countries have created different institutional mechanisms and different authorities in order to give effect to the legislative scheme. It seems that there are no standard models and the evaluation will have to be adapted to the specific country. However, in some circumstances in order to suggest ways to improve the functioning of the APED, the following questions could be asked:

- a) Is there a drug control administration?
- b) In which ways does this administration influence the APED?
- c) Which functions of the drug control administration are directly related to the APED?
- d) Describe these functions and evaluate their efficiency (registration, inspection, dissemination of information, etc.)

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5. ASSESSMENT OF EFFECTIVENESS

Assessment of effectiveness consists of an analysis of whether the results obtained are in accordance with the objectives of the APED programme; namely:

- regular supply at the primary health care level of effective, affordable essential drugs and vaccines; specifically, that at least 20 essential drugs will be available to 80% of the population within one hour's walk or travel
- improvement of the health situation through availability, accessibility and proper use of drugs and vaccines.

The evaluation proposed below is not very detailed but it can be carried out in a short period of time at the level of rural health facilities. To assess in depth effectiveness and impact will require much more detailed work at the community level (village health workers, community leaders, home level), in health centres, dispensaries and district hospitals. It will also involve work at the regional and national level.

5.1 AVAILABILITY OF DRUGS

At the periphery level, the best way to assess the availability of drugs is by doing a survey in a few health facilities to measure the actual stock of essential drugs and by performing interviews of the medical staff in these health facilities on the actual state of supply of essential drugs.

A. SURVEY

Objective: Analyse a representative sample of health facilities which serve under the APED programme in order to assess the availability of essential drugs.

Therefore the best way to choose the number of health facilities to be surveyed during the evaluation would probably be the following:

1. select the administrative units covered by the evaluation,
2. stratify the administrative units according to the time the units have been part of the programme,
3. divide each strata into smaller geographical units (clusters),
4. decide how many clusters can be covered time wise during the mission,
5. divide the number of clusters by the number of stratas,
6. if the number of clusters within each strata is roughly the same, select randomly as many clusters from each strata as the result given in point 5. If the numbers are not the same, select number of clusters in proportion to strata size,
7. if it will not be possible time wise to visit all health facilities within each cluster, stratify the material into, e.g. hospitals, health centres, dispensaries, etc., and continue as described in points 4, 5 and 6.

B. IN EACH HEALTH FACILITY (HF):

1. Evaluate the reliability of records (patient registers, stock replenishment costs, balance cards, etc.).
2. Note the drugs selected for the level of health care concerned that are actually in stock at the moment of inspection? the quantities of each? the date of the next replenishment? the date of the last replenishment?
3. Calculate, based on the number of treatment episodes over the last 3 months, for how long the stock of each essential drug is going to last.

4. Is there in stock drugs which are not selected for this level of health?

Essential Drugs in stock in each facility

Type of drug	Amount received during 3 months	Amount distributed during 3 months	Present stock	How long will this stock last
Chloroquine				
ORS				
Penicillin				
etc.				

This table gives answers to two questions:

- Are the essential drugs selected for the level of health concerned available?
- Are the stocks going to last till the next distribution?

C. INTERVIEW WITH PRESCRIBING STAFF/STAFF IN CHARGE OF HF

1. Are all essential drugs available now?
2. Is the drug supply improving, the same or getting worse?
3. How is the level of drug supply in general?
4. Are drugs received on a regular basis?
5. How frequently?
6. Which drugs are always supplied in short?
7. Which drugs are always supplied in abundance?
8. Are there any expired drugs in stock?
9. For how many weeks (or months) during the past year, have you been out of stock of critical drugs (chloroquine, penicilline, ORS ...)?
10. Do you think that new drugs must be added to the list?

In order to answer questions 6, 7, 8 and 9, the following table should be used:

Type of drug	Actual stock	Out of stock since 1-2 mths (wks)	Out of stock since 3-5 mths (wks)	Out of stock more than 5 mths (wks)	Comments including no information
Chloroquine					
ORS					
Penicillin					
etc.					

A table can be drawn, from the information collected in each type of HF of the sample; this table will facilitate the assessment of drug availability in general:

Type of HF: Type of drug	No. of HF's with stock	No. of HF's out of stock since 1-2 mths (wks)	No. of HF's out of stock since 3-5 mths (wks)	No. of HF's out of stock more than 5 mths (wks)	No info.
Chloroquine					
ORS					
Penicillin					
etc.					

D. EVALUATE SHORTAGE

If there is a shortage of essential drugs at the HF level, try to evaluate whether it due to:

- logistics problems (supply, distribution) (see 4.2)
- quantification of drugs
- irrational prescribing or inaccurate diagnosis (see 5.3).

Evaluate the weight of each component.

5.2 ACCESSIBILITY OF DRUGS

The APED coverage will be assessed by measuring the proportion of the population with hour's travel to health facilities which are part of the APED programme.

A. PHYSICAL ACCESSIBILITY

Physical accessibility indicates, the proportion of the population in the area with access to drugs at the health facilities.

Method 1: Map population distribution in relation to locations at which drugs are available. In the absence of population distribution maps, the estimate can be made by identifying the location of health facilities providing essential drugs and making a crude estimation of the number of people within the defined area.

Method 2: Evaluate physical accessibility through a one day survey on a sample of patients attending health facilities.

From this survey information can be obtained on:

- origin of the patient
- travel time (in different seasons)
- number of kilometers
- mode of transportation.

Method 3: Examine the records of patients at the health facility level and compare with the geographical distribution of the patients. (This approach can give a by-product: the differential utilization rate of patients coming from different distances).

B. UTILIZATION

1. Depending on the available data, try to evaluate:

- the yearly number of people who used to come to the health facility before the APED programme and now
- the yearly number of patients visiting a health facility not being served/being served by the APED programme
- the yearly number of patients at the referral level before the start of the APED programme and now
- the yearly number of patients at the referral level in an area not being served/being served by the APED programme.

All these figures will show the impact of the APED programme on the utilization of the health facilities and the shift between the treatment at the referral level and primary health care level.

2. Evaluation of the proportion of the population in need of services (or drugs) who have access to the health facilities and who actually do not use them.

From HF registers, record the number of individuals who contact the health facility (= numerator population for assessing coverage).

It is more difficult to evaluate the population in need of services or drugs but who do not use them; the best way is through community surveys (impossible to undertake during an evaluation).

During an evaluation, the only way to assess the utilization rate is to compare the rate of utilization of the health facility concerned with a normative utilization rate (average number of illness requiring medical care per year) if available.

3. In order to determine why people for whom the services (including essential drugs) are physically accessible, do not use them although they have need for them, try to evaluate the socio-economic accessibility of the services:

Economic barriers

- Do the people have to pay for the services?
- Do the people have to pay for the drugs?
- Are there other ways to obtain drugs freely in the district, mission hospitals, NGOs, etc.?
- Before the APED programme, did they pay for the services?
- What are the lowest levels of income in the population?
- Do they have to wait a long time at the health facility?
- What are the hours of opening of the health facility?
- Are these hours convenient for the people?

Socio-cultural barriers

- Are there many different ethnic groups in the area covered by the health facility?
- Are there problems between these ethnic groups?
- Are most of those attending the health facility from the same ethnic group?
- Is the personnel of the health facility from a particular ethnic group and is there a relationship between the number of attendants from one ethnic group and the ethnic group of the personnel at the health facility?
- Is there a common language or many vernacular languages?
- Does the personnel of the health facility concerned understand all the languages spoken by the patients?
- Is there a relationship between the number of patients speaking a particular language and the language spoken by the personnel?
- Does the health facility use translators?

- Are there certain beliefs which prevent people using the health facility? For example depending on the society concerned: Is the medical personnel too young? Is feminine personnel an obstacle to the use of the health facility (in society where women have an important social role)? etc.
- Where do they go first when they are sick:
 - traditional healers?
 - government facilities?
 - others?

5.3 PROPER USE OF DRUGS

How effectively are the essential drugs used in the health facilities serving under AP programme?

A. PRESCRIBING HABITS

- Looking at the outpatient registers, what are the prescribing habits of health workers like?
- Are drugs dispensed for conditions on which they have no therapeutic effects (such as antibiotics for a common cold)?
- Are two or more drugs used when one drug would be enough?
- Are drugs generally used for the correct indications? In the correct dosage?
- What training do health workers receive in pharmacology and therapeutics?
- Is this training reinforced in practice?
- Is there a manual for rural health workers to guide them in their clinical diagnosis and treatment of patients? If so, is this manual available to every prescriber?
- Are there standard norms for treatment? If so, are they followed?
- Try to compare the treatments given by the health personnel (through out patient registers) with the standard treatments included in their manual.
- Try to assess if the training and the manual have led to better diagnosing and prescribing practices.

B. DISPENSING METHODS

- What conditions exist at dispensing points?
- How are drugs handled?
- How accurately and cleanly are drugs dispensed?
- Is there a space organized efficiently in order to dispense drugs?
- Is simple equipment available (measuring vials, counting trays, etc.)?
- Who is responsible for the dispensing of drugs?
- What training do these individuals have?
- How much supervision do these people receive?
- What kind of packaging is used to dispense drugs to patients? e.g., individual packets filled on the spot from bulk containers or course of therapy packets filled out and labelled in advance?
- What kind of containers are used for hand dispensing drugs? Ziplock plastic bags, unsealed plastic bags, paper bags, pieces of paper, bottles, no containers, etc.?
- What type of labeling is used?
- What type of written instructions are given to patients; drug name, dosage (number of tablets, etc. to be taken), interval, mode of administration?
- Is symbolic labeling used?

C. PATIENT COMPLIANCE

- What is done to increase patient compliance?
- Is there time and space for the dispenser to speak with the patient and explain the use of the drug prescribed?

- Do health workers in the health facility visited know about factors in the culture that can affect patient compliance?
- Do they know the degree to which patients take drugs as prescribed?
- Do they believe that patient compliance has improved with the programme?
- What type of community education programmes are promoted? Are group health education sessions conducted? Are health posters related to the use of drugs displayed on the walls? In which language?
- What are the resources available for community education programmes?

5.4 CLIENT SATISFACTION

What does the population think about the APED programme?

- Quantitative assessment
(See section 5.2.B.)
- Qualitative assessment has to be done through a questionnaire addressed to patients in a sample of health facilities serving under the APED Programme.

Questionnaire (example)

- How long have you been coming to this health institution?
- Have the services improved during the last years?
- Are drugs more easily available?
- Do you see evidence that efforts are being made to improve the services?
- Do you get the kind of drugs you want?
(are drugs proposed relevant to the perceived priority needs of the population?)
- Do you get all the instructions you wish for the use of the drugs prescribed?
- Can you read the instructions on the labels?
- In the past, when there were no drugs available at the health facility, from where did you obtain drugs?
- Nowadays, do you still buy drugs outside?
- Which kind of drugs?
- When you are sick, where do you go first:
 - the health facility concerned?
 - the nearest hospital?
 - the traditional healer?
 - others?
- In the past, before the implementation of the programme, where did you go first?
- Do you feel that the health activities carried out in your village reflect the needs and the priorities of the population? (as expressed by them)
- Do you feel that these health activities (including the availability of essential drugs and vaccines) have improved the health status in the population of the village?

5.5 COMMUNITY INVOLVEMENT

Very often in programmes planned and controlled by the central authorities or by foreigners, the reaction of the communities is passive. This attitude should be seen as a signal that the community does not expect any real progress from the programme.

- Describe the mechanisms that exist for community involvement in health at regional/district level.
- How have these mechanisms been mobilized for health activities?
- How do they influence planning (give examples), utilization of services and drugs?

In the health facilities visited during the evaluation, some questions can be raised:

- Is there a development committee in the area? If yes, do health workers regularly participate?
- Is there a community health committee? If yes, does it meet regularly? Does it discuss health activities? Disseminate health information? Raise and collect contributions for health activities (drugs)?
- Does the community help in identifying individuals and groups with specific health problems?
- Does the community participate in the identification of health problems, e.g., lack of essential drugs, etc.?

A more in-depth study will need to be developed for interviews of community leaders.

5.6 MEDICAL ASSESSMENT OF EFFECTIVENESS

This indicator is very difficult to use for a programme that has not been running for long time. Secondly, improvements in health are not only due to the availability and accessibility of essential drugs.

A. VITAL STATISTICS BY REGIONS

Regions or districts	Crude birth rate year 19__ year 19__	Crude death rate year 19__ year 19__	Infant mortality rate year 19__ year 19__

Vital statistics by region or district can give some information on the differences between different years (with or without APED programme) and between different districts (with or without APED programme).

B. INCIDENCE OF SELECTED CONDITIONS REPORTED FOR THE LAST FIVE YEARS

It can be done mainly at the district/regional level or at the national level.

Year	Diph-theria	Pertus-sis	Neo-natal tetanus	All tetanus	Polio	Measles	TBC	Diarrhoea	Malaria	LBW chil-dren	Other
19..											
19..											
19..											
19..											
19..											
Trend*											

*Criteria will have to be set in order to determine if there is a significant trend in any direction for the diseases listed. For example, EPI has used the following criteria in programme reviews:
Significant decrease: reports available for each year, each subsequent year shows less cases than the previous year, in the last year the number of cases is less than half the number of cases in the first year.
Moderate decrease: reports available for at least 3 years, the majority of the reports show less cases than the first year, the last year at least 25% less than the first year.
No decrease: any other situation.

6. MANAGING THE ESSENTIAL DRUG PROGRAMME

6.1 PROGRAMME ORGANIZATION AND MANAGEMENT

A distinction will be made between the structure over which the programme has direct control and the structure through which the programme will have to operate. The former relates to the internal organization of the programme and financial management, and the latter relates to the drug supply system and the health care delivery system.

6.1.1 INTERNAL ORGANIZATION

Review of the performance (progress) of committees and management in relation to content (components) of the programme has been dealt with in section 4 (Analysis of Efficiency). This part of the procedures will therefore merely deal with the management process. The questions to be asked in evaluating the internal organization relate to:

a) Committees at central level

- What function do the programme committees have?
- Are they meeting regularly?
- Are long-term issues addressed, e.g., drug policy and strategy questions?
- Are minutes issued and followed up?
- Is there coordination with other programmes, e.g., EPI, CDD, MCH, etc.?

b) Committees at regional and district level

- Have regional and/or district level committees been set up to overlook the programme?
- What are their functions and how do they perform?
- Do they meet regularly and are field visits included?
- Who do they report to and what is the follow-up procedure?
- Is there coordination with other programmes, e.g., EPI, CDD, MCH, etc.?

c) Daily management

- Is the organizational structure suitable to the circumstances?
- What are the lines of authority and responsibility and are they in accordance with established job descriptions?
- Is there an informal decision structure?
- Do the expatriate staff play an advisory role or do they have executive power and what are the problems involved in this?
- How is the motivation of the staff (nationals and expatriates)?
- What are the career prospects and incentives?
- Does the salary scale cause a problem?
- Are the national staff likely to seek employment in the private sector and what are the means to retain them?
- Who do the staff supervise and which reporting system has been established?
- Is the staff qualified to perform their duties or do they need training in management skills?
- What kind of on-the-job training programme has been established?

6.1.2 FINANCIAL MANAGEMENT

The primary tasks of financial management are budget planning, funding and control of operations, and accounting for all resources employed.

In each of these broad areas, there is substantial room for applying simple or more sophisticated approaches, mainly depending on the way the APED programme is structured, the skills of management personnel, and on the scale of operations. A programme basically run as a government department on fiscal principles and rules applicable to classical ministries is unlikely to employ cash flow, capital budgeting and financial ratio analysis whereas chances of these tools of financial management being used increase with the programme's autonomy.

There is little information available in the form of actual descriptions of ongoing activities on these aspects of financial management. It is therefore proposed to start with some basic questions while indicating the direction of a somewhat more demanding evaluation in this field as results are obtained and APED programmes enlarge their scope.

A. BUDGET PLANNING

This is a catchword for management's role of projecting in a plan of operations the required financial resources in the form of recurrent and investment or capital funds. Careful allowance needs to be made for the consequences, in terms of recurrent funding, arising from past, present and projected investments in construction, equipment, vehicles and supplies of a useful life exceeding one year. Critical for the programme's implementation according to plans and commitments is accurate forecasting of the foreign exchange component for imports of drugs, associated supplies, fuel, vehicles and parts, and for investment in structures where local supplies are lacking. Lastly, budget planning needs to allocate resources by major programme components and in line with the expanding regional and local level network.

The pertinent questions, though subject to local circumstances, are likely to be:

- a) Timely planning and allocations of expected expenditures in the budgets of ministries and other public authorities (e.g. national tender boards) active or involved in the APED programme;
- b) Due allowance for expenditures to be made in foreign exchange at projected intervals and soliciting the actual commitment of external funds under negotiation or likely to be forthcoming;
- c) Presentation of budget plan in sufficient detail to distinguish investment from current outlays and among major cost categories for accurate accounting and financial performance appraisals;
- d) Active search for additional sources of finance, both internally (e.g. development banks, national insurance institutions) and externally. Is management active in exploring and proposing at the policy level the feasibility and mechanics of cost recovery or cost-sharing formulae?

B. FINANCIAL MANAGEMENT OF DAY-TO-DAY OPERATIONS

The financial management of day-to-day operations includes the diverse tasks of ensuring the availability of funds and releasing payments for expenses such as: purchasing drugs, materials and supplies including fuel as well as services, paying salaries, import duties and taxes if any, servicing short-term and longer-term debt on due dates and making allowance for depreciation of fixed assets by allocating a portion of the investment cost representing use, wear and tear during the reporting period to collective or several special reserve accounts.

On the revenue side, the tasks relate in corresponding fashion i) to the billing for deliveries and collection of payments due where drugs are being sold, ii) to the handling of credits obtained for current operations and capital acquisitions, and iii) to claims against suppliers arising from non-observance of contract terms.

Financial discipline and efficient management of the scheme as a whole are tested by evaluating first and foremost how current operations are being handled. Procurement procedures to obtain lowest prices internationally and astute placing of orders in a rhythm in line with likely turnover and related inventory requirements are probably the most eminent cost-containing measures on which to focus. More demanding are procedures dealing with detailed projections and subsequent monitoring of capital requirements; with cash flow management including short-term investments of liquid balances and hedging against foreign exchange risks; and with continuous financial performance control by cost centre and functions such as procurement, treasury, billing and collections and supervision of local outlets.

Questions establishing the record on performance in current operations can be derived from the above considerations and provide at the same time the occasion to test the ground during the evaluation as to management's interest in developing more efficient but also more demanding methods and tools.

C. ACCOUNTING AND AUDITING

This last section deals with accounting in a double sense: operating a reliable and transparent system of accounts, and accounting for all funds entrusted to management in the form of regular reports to supervisory and auditing bodies as well as to external sponsors of the programme. The pertinent questions are likely to be:

- a) Is the accounting system sufficiently developed to track transactions, inventories and capital equipment in use by programme components and down to local outlets?
- b) Does the accounting system enable comparative cost analyses by products, local outlets and user groups?
- c) Which improvements are now being made or are feasible to ensure the above?
- d) What purchasing, accounting and distribution rules and procedures are in use or could be improved to meet requirements of cost containment within standard frames and of safeguard against leakage of drugs into a secondary or black market?
- e) Which institutional modifications appear required to strengthen the financial management role at central, regional and local levels?
- f) For which functions and at which levels is training in financial management skills most urgently needed? What training facilities, programmes and instructional materials are in use and could be built upon?
- g) Is the programme being audited? by whom? how often?

6.1.3 DRUG SUPPLY SYSTEM

- a) Describe the organizational structure and relationship between the different units in the drug supply system (procurement unit), tender board, therapeutic committee, planning and finance units, import and inventory control units, medical stores at national, regional/district and health care level.
- b) Describe the functions and responsibilities of the different units.
- c) Assess the performance of each unit separately and in relation to the total structure.
- d) Suggest ways to remove bottle-necks and bureaucratic procedures.

6.1.4 HEALTH CARE DELIVERY SYSTEM

It is not the purpose of this evaluation to assess the general performance of the health care personnel but only their performance in relation to drug use (diagnosing, prescribing and dispensing practices). However, this has been dealt with in other parts of these evaluation procedures (see section 5).

6.2 BUDGETING, FINANCING AND COSTING

This section will review the structure and trends of health expenditures, with a view to finding ways of improving allocation patterns and generating increased resources. Such an analysis may point the way to possible cost savings and ways of streamlining operations.

6.2.1 PATTERNS OF HEALTH EXPENDITURE

- a) Present a table of expenditures, both planned and actual, by institution (e.g., Ministry of Health) for each year of the period under evaluation, and if possible, for a few years preceding the beginning of the programme. This should permit any interesting trends to be noted. Distinguish between local and government resources and external assistance; attempt to determine how much of the external assistance is on a grant basis, and how much will have to be repaid (if possible, note the interest rates of each source). Convert these amounts into local currency (using IMF exchange rate information from International Financial Statistics). Note significant differences between planned and actual expenditures, and significant increases or decreases in any given category of expenditure over time (for example, a significant drop in MOH budget allocations), and attempt to explain these (drop in price of main export, oil price rise, etc.).
- b) Analyse capital and recurrent expenditures of MOH budget by categories (personnel, drugs, materials, fuel and transport, maintenance, etc., including pro rata shares of capital depreciation for buildings and other significant investments, if possible).
- c) Analyse the role and importance of the private sector, where applicable. Include estimates of expenditures on drugs, private medical care including hospitalization, etc. Include estimates of expenditures of Social Security institutions if applicable. Although difficult to obtain, rough estimates of the importance of military medical and health care in terms of numbers of beneficiaries, number of staff employed, drug purchases, etc. may be very useful (may include police as well in many countries).
- d) With regard to external assistance, what types of projects and assistance have been provided? Have recurrent costs been adequately estimated and planned for? Is it possible to discern trends as to likely continuation and levels of assistance? Attempt to determine how much of the external assistance is on a grant basis, and how much will have to be repaid. Convert external assistance amounts into local currency (use IMF exchange rate information from Intl. Financial Statistics). (UNDP is usually an up-to-date and convenient source of information on external assistance.) Identify any external assistance in the area of drug supply and provide as much specific information as possible as to amounts of funding, activities, etc.

6.2.2 MANAGEMENT AND OPERATIONAL ASPECTS

- a) Assess the reliability and use by management of financial accounting, control, and auditing information. Focus in most countries will be on the Ministry of Health and the agency responsible for drug importation and distribution (Central Medical Stores or equivalent). What practical steps can be taken to improve performance in this area?
- b) Describe the situation with regard to foreign exchange. How scarce is foreign exchange? What is the mechanism for release of foreign exchange, and on what basis is foreign exchange released? What opportunities exist for achieving savings in foreign exchange? Are there any special arrangements with regard to foreign exchange in operation with specific countries, such as the CFA franc zone and the French franc? Briefly describe these.
- c) Present a "flow of funds" diagram, tracing the major steps in budgeting, authorizing payments, making disbursements, etc. with estimates of the time required at each step. Pay particular attention to the procedures for purchase of drugs. What could be done to shorten the pipeline and reduce the time required for each step?
- d) How are drug prices set? Who decides on this? What margin is applied? How do these prices compare with prices of similar products in the private sector?

6.2.3 ASSESSING COSTS

This is the most critical task--both for the sake of transparency among components and functional areas of the current programme and as a basis for continuous improvements or for costing alternative strategies. Costs need to be disaggregated and allocated in a manner reflecting actual occurrence in operations. Most pertinent are cost analyses i) by type of inputs, ii) by activity at various administrative levels, iii) by output in terms of services rendered at various echelons and iv) finally by user group or individual user.

Based on the earlier analysis of structure and operations, it is now easier to distinguish between fixed and variable as well as direct and indirect cost items, calculate various average and incremental (or so-called marginal) costs and thus establish signposts for a smoother flow of funds in operation.

Comparative cost analysis is employed to show how objectives of social equity, equal access, geographical equilibrium are being approached and met.

- a) Tabulate budget appropriations and actual application of funds by various levels of service delivery (e.g. hospital versus health centre dispensing) and by functional cost centres (i.e. procurement, storage, distribution).
- b) Present and interpret data for budgeted versus actually incurred costs for drugs by therapeutic class; trace the cost build-up from source (procurement) through process/handling stages with typical mark-ups to final dispensing and compare with earlier assumptions by concentrating on drugs accounting for, say, more than 20 per cent of total turnover.
- c) What kind and portions of indirect costs borne by the health care system at large can be allocated to the essential drug programme? Explain approach and rationale.
- d) Tabulate comparative costs by drug category, service levels, regions and in terms of urban/rural users to highlight equity aspects of the programme.
- e) What are the costs incurred by households to obtain access to service (i.e. transport to health centre, time lost for work) and what could be done to reduce these further?
- f) How do previously estimated and actual annual per capita costs for essential drugs and for pharmaceuticals at large compare? Current projections and rationale?
- g) What is the approximate outlay for drugs in absolute terms and as a portion of health care outlays by households in various regions and by income/wealth category?
- h) How much does this present in terms of disposable income of households?
- i) What is the cost of a complete course of therapy per treated patient in representative cases of morbidity? Distinguish by various age groups, social groups and groups at risk.
- j) What are the respective merits and problems with revenue generation by sale of drugs on a fee-for-service?
- k) What proportion of their income do households typically spend on essential drugs, on other prescribed medicines, and on freely available pharmaceuticals.

Several recent WHO documents provide explanatory detail and propose tabulations on specific aspects of assessing costs, e.g., reference (5) (15) annex 7, (6) page 28 and (8) page 80

6.3 MONITORING

Monitoring consists of the timely collection and review of a number of selected summary indicators which, when taken together, provide an adequate index of the programme's evolution through the execution and operation phases. In other words, the monitoring system shall report whether inputs, work schedules (activities), outputs and other required actions are proceeding according to plan. The monitoring system is mainly designed to provide the management of the programme with the information needed to follow-up activities on a day-to-day basis.

When evaluating a monitoring system it is first of all important to assess whether the chosen indicators describe the programme, objectives and implementation aspects, plus the targets, expectations and basic assumptions regarding each objective and aspect, that are to be monitored. Secondly, the processing and analysis of data should be evaluated; and thirdly, it is necessary to assess whether the monitoring results are presented in a digestible way and used in the decision-making process.

6.3.1 INDICATORS

The chosen indicators should have the following characteristics:

- a) They should cover the different aspects of implementation and operation of the programme. The indicators should provide information on the efficiency (chapter 4) and effectiveness (chapter 5) of the programme.
- b) They should be simple, and the number of indicators should be limited. The idea is not to have indicators which describes the total universe of the programme, but rather a few indicators which produce the information necessary for decision-making.
- c) They should be cost-effective. Just as it is not always necessary to have a separate indicator for each aspect of the programme, it is also not necessary to have full coverage of any particular factor. For example, a sample at a few health centers can be sufficient instead of collecting data continuously at every health center.
- d) They should be adapted to the manpower and financial resources of the country and, in particular, of the programme. Monitoring should not be based on complex and expensive data collection techniques that would be difficult to apply in the country on a continuous basis.

6.3.2 PROCESSING AND ANALYSIS OF DATA

In other monitoring systems the following major pitfalls have been experienced in the processing and analysis of data. Check to see if they also apply to the APED programme.

- a) lack of detailed planning
- b) lack of funds
- c) poor distribution of resources between data collection on one hand, and processing and analysis on the other hand
- d) establishment of unrealistic deadlines for producing monitoring reports
- e) too much data, which is usually a consequence of poorly selected indicators and/or overambitious sample size
- f) poor questionnaire design or inappropriate tailoring of the format of the questionnaire to the data processing capacity
- g) lack of delayed development of software and analysis procedures, as well as time-consuming validation processes
- h) not enough computer time
- i) inadequately trained personnel, insufficiently skilled staff for doing manual tabulations, lack of highly skilled expertise for computer processing of the data, overload of assignments, and high turn-over of staff
- j) field-level checking of data not institutionalized.

6.3.3 PRESENTATION AND USE OF MONITORING RESULTS

The presentation of monitoring results is as important as the design of indicators and processing and analysis of data. If reports are poorly written and/or presented, and very elaborate, they will not have the impact they deserve. The presentation should therefore avoid the above mistakes and include a summary that is issue- and problem-oriented. The whole process of maintaining a monitoring system is useless if the results are not used by the management in decision-making. Confront management with some of the problems brought in the monitoring reports and check to see if the information has been used and what action they have yet to do. This test is very important because it says something about the usefulness of the monitoring system and points to correction in the design.

7. ASSESSMENT OF INPUTS OF THE GOVERNMENT AND DONORS

In the preceding sections 4, 5 and 6 the evaluation has considered a large number of factors which have either contributed to or retarded programme progress. This section will deal with the inputs or rather the management/administrative support from the Government, WHO and other donors.

The following questionnaire can be used to indicate whether performance during the period covered by the evaluation has been negative, as anticipated or superior, and whether the factor has played an important role in programme performance. All factors judged to be not applicable should be so marked. Pertinent factors which do not appear in the questionnaire should be added in the spaces provided, as should any clarifying or explanatory comments.

	Not applicable	Performance vs. expectations			Check, if important
		Negative	As anticipated	Superior	
a. Support in preparing programme documents					
b. Guidance on programme background					
c. Guidance on national political/institutional situation					
d. Guidance on policy and legal aspects					
e. Guidance on administrative formalities					
f. Support in undertaking administrative formalities					
g. Support in recruitment of local staff					
h. Support in selection of local consultants					
i. Support in obtaining supplies					
j. Payment of salaries/allowances/expenses					
k. Provision of physical facilities and equipment					
l. Availability of secretarial help					
m. Provision of office material/equipment					
n. Provision of transport facilities					
o. Provision of storage facilities					
p. Maintenance and repair of equipment					

Other factors and/or comments:

	Not applicable	Performance vs. expectations			Check, if important
		Negative	As anticipated	Superior	
7.2 WORLD HEALTH ORGANIZATION					
a. Support in preparing technical parts of programme documents					
b. Support in developing technical strategy					
c. Overall adequacy of technical backstopping					
d. Support in preparing programme documents/revisions					
e. Guidance/assistance on design/evaluation methodology					
f. Timely provision of programme funds					
g. Response to requests for assistance					
h. Payment of salaries/allowances/expenses					
i. Coordination with related programmes (EPI,CDD,PHC)					
j. Timely recruitment of international staff					
k. Timely recruitment of international consultants					
l. Timely procurement of drugs, equipment and dressings					
m. Timely placement of fellows					
n. Timely reply to administrative consultations					
o. Guidance on policies and procedures of WHO					

Other factors and/or comments:

7.3 DONOR(S)

	Not applicable	Performance vs. expectations			Check, if important
		Negative	As anticipated	Superior	
a. Support in developing technical strategy					
b. Support in preparing programme documents/revisions					
c. Clarity/appropriateness of procedural guidelines					
d. Timely provision of programme funds					
e. Response to requests for assistance					
f. Support in recruitment of international staff					
g. Support in recruitment of international consultants					
h. Timely placement of fellows					
i. Timely procurement of drugs, equipment and dressings					
j. Timely replies to administrative consultations					
k. Guidance on policies and procedures of donor					
l. Coordination with related programmes (EPI,CDD,PHC)					

Other factors and/or comments:

7.4 OTHER PARTICIPATING AGENCIES

a. Timely procurement of drugs, equipment and dressings					
b. Timely replies to administrative queries					
c. Usefulness of replies to queries					

Other factors and/or comments:

8. PLANNING FOR THE FUTURE

In the event the programme is continuing, the following areas should be considered.

8.1 PROGRAMME PLANNING

Based on the overall conclusions and recommendations, the plan of operation and work schedules should be revised accordingly.

8.2 PROGRAMME OBJECTIVES

When revising the plan of operation the original programme objectives and immediate objectives (components) should correspond with the future needs.

8.3 PROGRAMME STRATEGY

Will the strategy remain the same in the future, e.g., is there a need to shift the balance between the components or has one component been completed and therefore must be deleted, etc.?

8.4 MANAGEMENT

Based on the revised Programme Plans, Objectives and Strategy is there a need to change the organizational set-up of the programme? Must terms of reference for committees and job descriptions for individuals be rewritten?

8.5 FEASIBILITY

If the evaluation recommends an expansion or extension of the programme, then it is very important to analyse whether the programme will be economically and financially feasible for the Government in the future. In earlier sections of these procedures, the efficiency of the programme has been analysed within the present programme set-up. In planning for the future, sources of finance in the form of, e.g., cost recovery and price policies might have to be considered in order to make the programme affordable for the Government. By "cost recovery" is meant a system whereby a portion of the cost of drugs and/or a consultation is borne by the patient. By "price policy" is meant a system whereby cost recovery is based on the patient's ability to pay and/or the relative importance of the drugs.

8.6 EXTERNAL ASSISTANCE

Finally, the need for future assistance from WHO and/or other donors should be assessed. Future assistance might take a different form than when the programme was designed and probably should, because the country in the long run will have to cover all public expenditures for the programme itself.

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MANUAL FOR CONDUCTING AN EVALUATION OF AN
ACTION PROGRAMME ON ESSENTIAL DRUGS (APED)



MANUAL FOR CONDUCTING AN EVALUATION OF AN
ACTION PROGRAMME ON ESSENTIAL DRUGS

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I. PHASES AND STEPS OF AN APED EVALUATION

In general, an APED evaluation (hereafter called evaluation), is carried out in an intensive team effort over a relatively brief time period (in the order of three weeks). However, to prepare for the optimal use of the evaluation team during that period, considerable preparation is mandatory. In fact, one might argue that the benefits derived from the evaluation are proportional to the quality and the thoroughness of the planning.

For that reason, the evaluation is partitioned into six phases, the first three of which are devoted to the planning. These phases are:

- A. Initiation Phase
- B. Design Phase
- C. Administrative Preparation Phase
- D. Field Work
- E. Analysis Phase, including planning for the future
- F. Documentation Phase.

In turn, each phase is partitioned into steps; some pertaining to concept and others pertaining to logistics. The discussion of each phase will include a listing of the steps and a commentary of variable length on each step. The reader is cautioned to approach the application of the steps with an open mind - each needs to be applied judiciously within the context of the given evaluation. The steps and the implied sequence are presented as a guide through the programme evaluation process, not as a prescription which must be followed at all costs.

A. INITIATION PHASE

The steps in the initiation phase are:

1. Take the decision to proceed with the evaluation based on assessment of the needs of the country and the usefulness of an evaluation in meeting those needs.
2. Assign responsibility for the conduct of the evaluation.
3. Identify supporting and participating agencies, both national and international.
4. Set the dates for the evaluation.

1. Take the decision to proceed with the evaluation. Prior to initiating an evaluation, it is essential that the needs of the country be identified and that careful consideration be given to the role an evaluation might play in meeting those needs. In the past, evaluations have been quite useful because they provide an opportunity:

- (a) to measure the progress made towards implementation of an essential drugs programme in terms of the extent to which well defined goals for improvement of availability of drugs, accessibility of drugs, proper use of drugs, client satisfaction and community involvement have been achieved.
- (b) to identify obstacles to continued progress, and identify those elements which are developing well and according to plan;
- (c) to identify areas where research needs to be conducted in order to improve the programme;
- (d) to validate routinely monitoring data regarding programme implementation in the country; and
- (e) to gather data not normally a part of a country's information system, especially data on the process of implementation not easily codified in routine data collection systems.

2. Assign responsibility for the evaluation

In order to increase the probability of success of an evaluation, it is advisable to assign clear responsibilities for the evaluation to appropriate individuals and the steering committee of the programme.

3. Identify supporting and participating agencies

One factor which has contributed to the success of completed evaluations is the diversity and breadth of the team ultimately charged with carrying out the evaluation. Early on, it is advisable to identify all international agencies and any non-governmental organizations who play a role in the delivery of essential drugs. These groups should be informed of the intention to do the evaluation and, where appropriate, efforts should be made to secure commitments as to their participation.

4. Set the dates for the evaluation

It is imperative that the dates of the evaluation are set as early as possible. Because of the many scheduling difficulties and logistical obstacles which arise in any programme evaluation, it is essential that dates be fixed early in the process so that work on resolving the practical problems associated with the evaluation can proceed in a definitive way.

A most important date is that of the post-evaluation meeting (section E.3) at which high-level officials act on the findings of the evaluation in reformulating policy and reshaping the plan of action for implementation. The commitment of the appropriate officials to dedicate adequate time to the post-evaluation meeting must be secured well ahead if the meeting is to be held on schedule and without interference from the routine demands of government service.

B. DESIGN PHASE

The steps in the design phase are:

1. Review and make a preliminary analysis of existing information.
2. Collect information about the programme.
3. Collect data relating to the achievement of stated objectives and project performance.
4. Draw the sample for assessment of effectiveness.

5. Design the data collection (survey) instruments.

6. Field test the survey instruments.

1. Review and make a preliminary analysis of existing information

It is important to assemble a great deal of information prior to the field work phase of an evaluation. A first step is the gathering of general information of the country and the health care system (see section 1 in "PROCEDURES").

A second step should be collection of macroeconomic and social data influencing the programme (see section 3 in "PROCEDURES").

2. Collect information about the programme

All the information about the programme should be collected before the beginning of the field work phase. This might include:

- a) Policy statements, circulars and ordinances regarding the programme, existing plans for implementation, etc. (see section 2 in "PROCEDURES").
- b) Programme objective and immediate objectives, inputs, activities, outputs, indicators and assumptions of each component of the programme (see section 4 in "PROCEDURES").
- c) Any past evaluations of the programme or its separate components
- d) All relevant monitoring data.

3. Collect data relating to the achievement of objectives and project performance

Considerable time will be saved by the evaluation team if data related both to the achievement of objectives (as reflected by selected indicators) and project performance (as reflected by inputs achieved, activities undertaken, and outputs produced) are collected beforehand. Objectives, assumptions, indicators, etc. should not be altered at this stage, either in order to reflect the current status or in anticipation of the evaluation findings.

4. Draw the sample for assessment of effectiveness

The selection of a sampling scheme requires that a balance be struck between cost and precision and that the scheme is feasible given logistical and time constraints. The proposed assessment of effectiveness (see section 5 in "PROCEDURES") is not very detailed and can be carried out in a short period (7 days) at the health centre/dispensary level. Should it be decided at a later stage to conduct an evaluation at all levels of the health care system, e.g. community level (village health workers, community leaders, home level), health centers/dispensaries and district hospitals, the question of drawing a sample becomes much more complicated.

Note, the selection of the sampling scheme is a prerequisite for determining the manpower needed for the field work phase. During that phase, enough staff must be on hand to complete the field work within the designated time. Estimates of staff required can be made only when the number of sites to be visited and their relative accessibility are known. Also, transportation requirements and budgetary needs can be fixed only after the sampling scheme is defined and the staff needs determined.

5. Design the survey instruments

Generally, this step "pins down" the exact nature of the evaluation by defining exactly the field data to be gathered. Within the context of a programme evaluation, it is necessary to balance the breadth of each instrument against the depth, the desire for quantitative data against the need for quick and easy analysis, and the flexibility afforded by open-ended and opinion type questions against the clarity and simplicity of highly structured coded questions.

6. Field test the survey instruments

If a survey is to use newly developed untried instruments of data collection, then they should be field tested first. Such a test should:

- a) confirm the feasibility of the package of survey instruments, especially the clarity of each question and the timing required to complete the entire process of data gathering;
- b) confirm the feasibility of using the entire package of survey instruments in a selected geographical area given the timing and other logistical constraints.

Clearly, the field test could lead to appropriate modification of the original survey instruments.

C. ADMINISTRATIVE PREPARATION PHASE

The first two phases deal more with the development of the conceptual framework for the evaluation. In this third phase, the more mechanical aspects of the evaluation are attended to. As we noted earlier, these mechanical aspects are as critical to the success of the evaluation as are the conceptual aspects. Therefore, we urge that this phase begin as early as possible; in fact, much of this phase can be done in parallel with the first two. The steps in the administrative preparation phase are:

- 1) Form the team which will conduct the evaluation.
- 2) Form a proposal as to how to partition the larger team into smaller survey teams.
- 3) Make all the logistical arrangements for the field work.
- 4) Secure the required national and international financial support.
- 5) Arrange for training and working facilities at central and provincial levels.
- 6) Arrange for translators, guides and, most importantly, secretarial support for the entire field visit phase.

1. Form the team which will conduct the evaluation

One of the first pertinent administrative decisions is the formation of the evaluation team. This decision is taken considering issues relating to both the size and the composition of the team.

As the evaluation is technical, the composition should reflect this. Members should, a minimum, have the following background:

- physician
- health educator
- health economist
- sociologist
- pharmacologist

and be drawn from the following groups:

- Ministry of Health
- Ministry responsible for procurement of drugs
- Ministry responsible for local production
- WHO
- International agencies playing a role in the development of the programme.

Note, the team should not include persons who would be evaluating their own work. Also, the team cannot consist solely of international or external agency personnel as it is a country evaluation.

Finally, note that international participation must be arranged and confirmed far ahead of the anticipated dates of the evaluation. Such arrangements should be with specific individuals within the international agencies as well as with the agencies themselves.

2. Partition the evaluation team into smaller survey teams

The larger evaluation team should be partitioned into smaller survey teams. Each survey team must act in parallel with the others, but as a self-contained independent unit during the gathering of data in the field.

3. Make all logistical arrangements

Once again, we reiterate the absolute requirement to arrange all logistical aspects of the field work in advance. In this step, we emphasize the more mundane arrangements, including:

- a) hotel bookings, both central and in the field;
- b) vehicle reservations, including petrol and drivers, and;
- c) within country airline reservations, if needed.

4. Secure the required national and international financial support

Programme evaluation of the programme is not an inexpensive activity. If the evaluation is not part of the regular budget of the programme, other sources must be sought, e.g., national and/or international resources.

In estimating costs, one might consider using the form in Annex 1.

A comprehensive budget should be prepared, and revenues should be identified as to source.

5. Arrange for working facilities at central and provincial levels

In addition to arranging all of the logistical aspects of the survey (step 3), it is necessary to arrange the facilities for the survey teams to do their "office" work (data tabulation, analysis and report writing). The teams will need facilities at both central and provincial levels.

6. Arrange for translators, guides and, most importantly, secretarial support for the entire field visit

Translators may be needed to assist international team members with documents prepared in local languages. More importantly, translators may be needed to assist in the field work in areas where local dialects serve as primary languages.

Secretarial support is critical at all phases of the field visit - not merely for report writing at the end. Often, evaluation teams begin preparing draft materials at the start of the evaluation for both intra-team exchanges and for later use in the final report.

D. FIELD WORK PHASE

The field work phase is envisioned as a short but intensive phase carried out by the entire evaluation team. It consists of only two steps:

- 1) Conduct surveys at the health center/dispensary level and visit the regional and district health authorities.
- 2) Perform a "first level" data analysis.

1. Conduct surveys at the health center/dispensary level and visit the regional and district health authorities

A major activity in the evaluation process is the collection of essential data at the health center/dispensary level, but the regional and district health authorities shall also be visited in order to get a full picture of the programme's efficiency and effectiveness.

2. Perform a "first level" data analysis

The "first level" data analysis consists of the summarization (in most cases, the totalling) of the responses to each question from the field survey.

E. ANALYSIS PHASE

The analysis can be achieved in four steps.

- 1) Conduct the second level data analysis.
- 2) Prepare a preliminary report, including data summaries, findings, conclusions and recommendations.
- 3) Prepare the plan of action for implementing short-term solutions.
- 4) Present and discuss preliminary conclusions and recommendations with decision-makers (post-evaluation meeting).

1. Conduct the second level data analysis

Upon returning from the field, the team should create master files of the survey instruments and the summaries generated during the first level data analysis. The second level data analysis consists of the compilation of the relevant summaries of the entire data collection activity from the preliminary summaries or, where necessary, from a return to the original survey instruments.

2. Prepare a preliminary report, including data summaries, findings, conclusions and recommendations

A preliminary report should be prepared as quickly as possible including summaries of the relevant data, interpretations, findings and conclusions derived from the summaries, and recommendations. Data should be presented in simple tables, using easily understood modes of presentation. Consolidation of the data into fewer variables is desirable. The source for all data should be cited and all tables should be titled and clearly labelled.

3. Prepare the plan of action for implementing short-term solutions

One of the most valued outcomes of the evaluation is a plan of action for implementing short-term solutions. Preparation of this plan should be done by the evaluation team itself.

4. Present and discuss preliminary findings, conclusions, recommendations and plan of action with decision-makers (Post-evaluation meeting)

The success of the programme evaluation is reflected in the response of decision-makers to the pertinent findings. The magnitude and quality of that response are likely to be enhanced if the evaluation team reviews all its findings, conclusions and recommendations with the appropriate decision-makers before the team is disbanded.

F. DOCUMENTATION PHASE

The documentation phase consists of one step: the preparation of the formal evaluation document. This can be done more slowly, after the evaluation team has ended its intense field visit. It is important to prepare a formal report to create a record of the evaluation, to provide a tool for those charged with implementing the recommendations of evaluation, and to leave a basis for subsequent evaluations. Moreover, in the event that the final publication of the report is to be done by an international agency, it is important that a draft of this document be left, in-country, by the evaluation team.

II. TIMING

The underlying assumption for the evaluation process is that the entire evaluation - from decision to start to submission of the report - be completed in approximately six months and that the actual field work and analysis phase be completed within approximately 3 weeks (a 3-week schedule is given as annex 2).

ANNEX 1

SUGGESTED BUDGET FRAMEWORK

	Proposed Budget	sources of funds
1. <u>Preparatory phase</u>		
1.1 Evaluation preparatory meeting:		
Meeting facilities		
Participants		
Travel cost		
Secretarial support		
Stationary/miscellaneous supplies		
Others		
1.2 Field testing of methodology/survey forms:		
Participants		
Travel cost		
Stationary/printing forms		
1.3 Duplication/distribution of background doc.		
1.4 Other expenses		
2. <u>Evaluation</u>		
2.1 Evaluation team meeting:		
Meeting facilities		
Participants		
Travel cost		
Hospitality/miscellaneous		
2.2 Field survey:		
Daily allowance		
Internal travel		
Rental of vehicles		
Petrol,oil,lubricants,maintenance,repairs		
Drivers, guides, interpreters		
Others		
2.3 Stationary and administrative cost		
Compilation/distribution of draft report		
Secretarial support		
3. <u>Publication of final report</u>		
Compilation		
Translation		
Editing		
Printing		
Distribution		
4. <u>Others</u>		
.....		
.....		
<hr/>		
TOTAL		
Additional contribution from bilateral/ multilateral agencies		
Grand total		
Number of consultants person/weeks funded by		

TIMETABLE OF ACTIVITIES DURING THE EVALUATION

ANNEX 2

<u>Activity</u>	<u>Day</u>
1. Assembly of evaluation team members	0
2. Meeting of evaluation team	1
3. Assignment of team members to field visits	1
4. Explanation of objectives, methods and instruments	1 and 2
5. Administrative preparations for field visits	1 to 4
6. Collection of data at the central level	2 to 4
7. Tabulation of central level data and preparation of short report on findings at Central level	4
8. Field visits	5 to 13
- travel to field	5
- training of interviewers	5 to 7
- collection of data	7 to 12
- tabulation of data	7 to 12
- travel back from field	13
9. Plenary session and presentation of field team reports (Identification of achievements and problems and tabulation of data)	14 (half day)
10. Dividing into subgroups to discuss relevant areas	
Preparation of lists of achievements, problems and recommendations with a plan of action with timetable for implementation for each area	15 to 18
11. Preparation of draft summary of findings, conclusions and recommendations	19
12. Plenary session to summarize findings, conclusions and recommendations	20
13. Presentation of summary of findings, conclusions and recommendations to Ministry of Health	21
14. Preparation of draft final report	22 onward

